Summary of the Proficiency Testing Committee Meeting Tuesday, July 29, 1997

The Proficiency Testing Committee of the National Environmental Laboratory Accreditation Conference (NELAC) convened on Tuesday, July 29, 1997, 12:30 - 5:00 p.m. The meeting was led by its chair, Ms. Andrea M. Jirka. A list of action items is given in Attachment A. A list of participants is given in Attachment B.

INTRODUCTION

Ms. Jirka introduced members of the Proficiency Testing Committee. She noted that two members (Dr. Barbara Erickson and Mr. Fred Grunder) will be rotating off the committee. They will be replaced by Ms. Lara Autry, EPA Emission Measurement Center, and Ms. Darlene Raiford, Hampton Roads Sanitation District. In addition, Ms. Anne Rhyne, TNRCC, has been elected as committee chair.

Ms. Jirka indicated that this was a challenging task ahead of the committee. She appreciated the interest and willingness of the participants, but noted that there was still a lot of work ahead. The objective of this meeting was to finalize the draft PT Standard in preparation for the NELAC vote. She recognized that there are a lot of good opinions and ideas. However, the final product must reflect the conference decisions in a democratic process. Participants must be flexible and willing to compromise.

BACKGROUND

There are five current documents: Chapter 2 and four completed appendices. Chapter 2 comprises the main document of the Proficiency Testing Program. Four appendices are completed, three additional appendices are in progress (radiation, biology, microbiology), and an appendix for air analyses is planned.

CHAPTER 2

Ms. Jirka presented an overview of Chapter 2. She noted that the chapter has been improved numerous times based on feedback from a variety of sources. She noted also, that PT is only one part of the accreditation process.

EMMC Recommendations

Ms. Jirka introduced Jan Jablonski (US EPA, ORD) who presented EMMC's proposed changes.

Ms. Jablonski referred to a memo dated July 25, 1997, from the EMMC Laboratory Accreditation Panel Tri-Chairs. The memo presents a review of the current EPA Panel position. All of the

issues presented in the memo were discussed and completely resolved to the satisfaction of the EMMC except for three:

- 1. Use of a single sample.
- 2. PT Providers providing samples on a fixed schedule.
- 3. PTOB certifying individual samples.

In addition, Ms. Jablonski suggested a new section at the end of Chapter 2 (proposed Section 2.8). She indicated that the EMMC Panel could vote in favor of Chapter 2, if their recommendations were accommodated.

Issue of Single Sample

It was noted that different analytical procedures used by different laboratories require concentration ranges that cannot be covered by a single sample. It was suggested to take out "single sample" altogether. Another contributor agreed with this idea, saying that this would eliminate restrictions that may exist in the future.

It was moved and seconded that "single sample" be changed to "single concentration." The PT Committee voted and approved the motion unanimously.

It was noted that there is still a problem with the number of samples per year. EPA cannot, for example, provide more than one DMQR sample per year. After discussion, it was generally agreed that although EPA will continue to require one sample per year in this program, NELAC will require two. Additional samples must be acquired from other than EPA.

Issue of Providing Samples on a Fixed Schedule

Currently the document calls for the schedule to be set by the PTOB. Providers have the flexibility to offer PT samples on an "on demand" schedule, if they desire. It was noted that a non-specific random schedule will be a burden to the states. Many states suffer from a lack of sufficient staff. Many studies of the various programs coming at once will be an administrative challenge. It would be better to sequentially schedule the studies and process the data systematically. States would have an easier time if the studies were performed on a established schedule. A poll was taken to see if the state representatives preferred a fixed schedule. In the straw poll, fifteen agreed and two did not. It was noted that the question of what the fixed schedule will be is not resolved. It was added that the availability of a national database would simplify the work of the states.

One person noted that a single national schedule would be acceptable if the studies were spread throughout the year. Another noted that a potential problem for providers is supplying samples to a very small number of laboratories on a fixed schedule.

A motion was made stating that PT studies occur at fixed times per year, with the number not set, and that initial and remedial samples can be obtained outside these schedules. There was no second and the motion failed.

Another motion was made to have two studies per year. No second was made and the motion failed.

Another motion was made to have four studies per year. No second was made and the motion failed.

Another motion was made that Section 2.7.3 state that there be "periodic PT studies at fixed times per year on a schedule to be determined, and that initial and remedial samples can be obtained at other times." The motion was seconded and approved.

Another motion was made to add to the end of the first sentence in Section 2.7.3, "as set by the primary accrediting authority." The motion was seconded and passed, three to two..

Issue of PTOB Certifying Individual Samples

It was noted by a PT Committee member that the intent is to have the PTOB oversee the process and the products, and not to approve individual samples. It was moved that language be added to Section 2.2.3, as described in the committee errata sheet, to clarify this issue. A second was made and the motion passed unanimously.

Issue of PTOB as Accreditor

It was noted that this issue is already covered in the previous vote on Section 2.2.3.

It was noted that NIST procedures and methods of operation are under development, some of these items come under Federal regulations which the Agency cannot change. To deal with this problem, the EMMC recommended that a Section 2.8 be added stating that NELAC set standards in agreement with EPA and NIST procedures and methods. Extensive discussion ensued on the roles and responsibilities of NELAC, EPA and NIST. It was noted that EPA, NIST, NELAC and other stakeholders will work together. After prolonged discussion, agreement could not be reached on appropriate language. Finally it was proposed that this question be addressed in a resolution from the floor during the day of voting and it not be addressed directly in the chapter. The EMMC withdrew its proposed addition to the chapter.

Errata Sheet

Ms. Jirka reminded the contributors of the errata sheet in the package. There are three points presented which have been approved by the PT Committee. These are:

1. The PTOB, and not NELAP, will approve or disapprove PT providers.

- 2. The PTOB will conduct regularly scheduled on-site audits biennially, rather than annually.
- 3. Two paragraphs describe the effective standards that are in place until NELAC is operational in September, 1998. These paragraphs are to be Section 2.0

ELAB Recommendations

Mr. Tom Coyner presented six recommendations from the ELAB committee regarding Chapter 2. These are:

- 1. ELAB recommends that EPA prepare a working set of PT sample design criteria which meet Program Office requirements to be used by the Proficiency Testing Oversight Body (PTOB) to include, at a minimum, concentration, interferences, media.
- 2. ELAB recommends that NELAC/NIST/EPA develop a protocol which can be used by the PTOB through review and analysis of data to assure program equivalence among PT Providers. ELAB further recommends that this protocol be finalized as soon as possible to ensure the integrity of this program.
- 3. ELAB recommends that the periodic PT studies occur at fixed times throughout the year. ELAB further recommends that initial and remedial PT samples may be obtained outside this schedule.
- 4. ELAB recommends that the long range goal of NELAC be to develop a consistent approach to both scope of accreditation and PT program sample design which recognizes the needs of the laboratories, the primary accrediting authorities, and the Agency, particularly with regard to performance based methods, similar technologies, and analytical capabilities.

 ELAB recommends that the PTOB, during implementation of the PT program, require
 - that each PT provider record and report PT results to both the accrediting authority and the PTOB on a method basis, by matrix and analyte.
 - ELAB recommends that a task group monitor the impact on implementation of the discrepancy on PT program design and the scope of accreditation.
- 5. ELAB recommends that there be consistency between the NELAC Standards and the EPA PT Externalization program.
- 6. ELAB recommends that the proposed PT standards (including the Appendices) be adopted as presented.

These are implementation issues and consistent with the current chapter. He further added that field of testing by analyte/matrix approach as recommended by the NELAC PT Committee is compatible with the method approach as recommended by the ELAB PT Committee.

Further Discussion of Chapter 2

A contributor asked about the difficulty of getting into the provider business because of the NELAC restrictions. It was acknowledged that the level of playing field has been raised but that there is no intention of restricting the formation of new PT providers. One issue raised was the requirement for 20 data points for a study to develop pass/fail criteria. In response, it was noted that the PTOB can waive this requirement under appropriate circumstances.

In response to a question, it was noted that any decision about the accreditation of a laboratory is completely the decision of the accrediting authority. Decisions are not made by providers.

APPENDIX A

Tom Coyner presented a section by section overview of Appendix A.

In the following discussion, it was clarified that same sample could not be used at different times.

Another issue raised was the certification of true values. Use of different methods may lead to different results due to parameters such as differences in interferences and chemical used to prepare the test samples. In response, it was noted that EPA Programs and others will need to provide the PT providers with development and sample design criteria to minimize such problems. This will be covered in Appendix B.

In regard to the data available to subscribers, it was noted that a laboratory may request all data from a provider. It was also noted that obtaining statistical results describing other laboratory's performance should not be a problem, and the description of data to be available will be expanded in the next generation of this document.

It was noted that the last sentence of A.6.0 conflicts with 2.6.1. Algorithms are given to the PT Providers but not the community. This was acknowledged to be true, and needs to be further examined.

The issue of inadequate PT samples was raised. It was noted that the PT Providers must maintain liability for their samples.

Confusion was noted in Section A.4.0 dealing with sample design and the review process. There seems to be inconsistency with NIST. To deal with this, it was moved to delete the last two sentences of this section. The motion was seconded and passed unanimously.

APPENDIX B

Mr. Chuck Wibby presented an overview of Appendix B.

In the following discussion, it was noted that the language in B.4.0 is not as strong as in Appendix A. It was moved that a sentence be added to the end of the section, "All PT samples must meet all applicable specifications published by EPA and/or NELAC." The motion was seconded and passed 4 to 1.

The 50% RSD requirement was questioned as being insufficiently narrow. This would be a concern when providers are not meeting requirements or producing inadequate samples. In response, it was noted that the general design must be approved by the PTOB. It's the decision of the PTOB whether or not a change is trivial. This requirement should delay product development or change in concentration ranges.

It was suggested that the effects of shipping stress be tested with each sample type.

A question was raised on what happens if a sample fails the stability test. In response, it was noted that the data is not used until the issue is resolved. In the worst case, the provider would assume fiscal responsibility and the laboratories would run another sample. This will be addressed further in the next generation of this document.

APPENDIX C

Mr. Matt Caruso was to provide an overview of Appendix C, but time did not permit this. Instead, discussion started immediately.

Someone asked if a sample is invalidated if some given percentage of the laboratories fail a sample. Another expressed concern about the level of detail of criteria to approve providers relative to sample performance. In response, it was noted that a 100% fail rate or 100% pass rate may be a real problem, but acceptance rate is not the only criteria.

It was noted in Section C.1.1.2, algorithms will be used to score PT samples and the PTOB will be the source of these algorithms. This is not the role of the PTOB. In response, it was moved that "PTOB" in Section C.1.1.2 be changed to "EPA or its designee." There was no second and the motion failed.

There was confusion about the derivation of the mean and standard deviation from a true value. It was added that our concern should be about getting the right answer rather than appropriate methods. It was agreed that this discussion needs clarification.

APPENDIX D

This appendix, which was to be presented by Ms. Ann Rhyne, was not presented or discussed due to lack of time.

CLOSURE

Ms. Jirka thanked everyone for their input and efforts and the meeting was adjourned at 5:05 p.m.

ACTION ITEMS Proficiency Testing Committee July 29, 1997

Item No.	ACTION	Date Completed
1	Vote on acceptance of Chapter 2 and Appendices A, B, C, and D	7/31/97 Passed
2	Resolution to deal with impact of Federal regulations on NIST program/procedures development.	Resolution Passed
3	Clarification in Appendices as needed.	Ongoing

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